UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
REGION 5
77 WEST JACKSON BOULEVARD
CHICAGO, IL 60604-3590

JAN 24 2011

REPLY TO THE ATTENTION OF:

AE-17J

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Robert D. Morrison
Divisional Vice President, Environmental, Health, Safety and Energy
Abbott Laboratories
1401 Sheridan Road
North Chicago, Illinois 60048-4000

Re: Notice of Violation and Finding of Violation
Abbott Laboratories, North Chicago, Illinois

Dear Mr. Morrison:

This is to advise you that the U.S. Environmental Protection Agency (EPA) has determined that the Abbott Laboratories' (Abbott or you) facility at 1401 Sheridan Road, North Chicago, Illinois (facility) is in violation of the Clean Air Act (CAA) and associated state or local pollution control requirements. A list of the requirements violated is provided below. We are today issuing to you a Notice of Violation and Finding of Violation (NOV/FOV or notice) for these violations.

Emission units at Abbott are subject, in part, to comply with the regulations included in the facility's CAA Title V operating permit; with Subpart A – General Provisions of Part 63 – National Emission Standards for Hazardous Air Pollutants (NESHAP) for Source Categories; with Subpart GGG – NESHAP for Pharmaceuticals Production; and with the Illinois State Implementation Plan (SIP).

On February 1, 2010, Abbott submitted a malfunction letter to EPA, Region 5 and the Illinois Environmental Protection Agency (IEPA) in accordance with 40 CFR § 63.1260(i)(2) and 40 CFR § 63.10(d)(5)(ii). Region 5 received the letter on February 3, 2010, in which Abbott indentified violations at the North Chicago facility that resulted from a malfunction that occurred at the regeneration steaming temperature continuous monitor, along with subsequent malfunctions of the adsorption timer and alarm system.

Based on events reported in Abbott's February 1, 2010 letter, EPA finds that Abbott is in violation of the following:

1) Regulations in Subparts A and GGG of the NESHAP, as incorporated into Abbott's Title V operating permit, requiring that the procedures specified in the facility's startup, shutdown and malfunction plan (SSM Plan) are followed. Abbott did not follow its SSM Plan on January 23 and 24, 2010.

2) Regulations in Subpart GGG of the NESHAP, as incorporated into Abbott's Title V operating permit, requiring that compliance with emission limits be demonstrated, in part, by complying with adsorption cycle time and regeneration frequency provisions. Abbott deviated from its allowable maximum adsorption time on January 23 and 24, 2010.

3) Regulations in Subpart GGG of the NESHAP, as incorporated into Abbott's Title V operating permit, requiring that hazardous air pollutant (HAP) emissions be reduced by 98 percent. Abbott failed to reduce methylene chloride (also known as dichloromethane) emissions by 98 percent on January 23 and 24, 2010.

4) Regulations in Subpart GGG of the NESHAP and the Illinois SIP, as incorporated into Abbott's Title V operating permit, containing HAP mass emission limits. Abbott exceeded methylene chloride mass emission limits as a result of HAP emissions which took place on January 23 and 24, 2010.

EPA finds that the Abbott facility has violated the above listed NESHAP and Illinois SIP requirements, as incorporated into Abbott's Title V operating permit. Since Abbott violated its Title V operating permit, it has also violated Title V of the CAA and its associated regulations which require compliance with terms and conditions of Title V permits. Additionally, in violating the Illinois SIP requirements, you have violated Title I of the CAA and its implementing regulations, which require compliance with the terms and conditions of the Illinois SIP.

Section 113 of the CAA gives EPA several enforcement options to resolve these violations, including: issuing an administrative compliance order, issuing an administrative penalty order, bringing a judicial civil action and bringing a judicial criminal action.

We are offering you the opportunity to request a conference with us about the violations alleged in the NOV/FOV. You should request a conference within 10 days following receipt of this notice. Any requested conference should be held within 30 days following receipt of this notice. This conference will provide you a chance to present information on the identified violations, any efforts you have taken to comply and the steps you will take to prevent future violations. Please plan for your facility's technical and management personnel to take part in these discussions. You may have an attorney represent and accompany you at this conference.

The EPA contact in this matter is Monica Onyszko. You may call her at 312.353.5139 if you wish to request a conference. EPA hopes that this NOV/FOV will encourage Abbott's compliance with the requirements of the CAA.

Sincerely,

Cheryl L. Newton
Director
Air and Radiation Division

Enclosure

cc: Ray Pilapil, Air Quality Division
Illinois Environmental Protection Agency

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
REGION 5

IN THE MATTER OF:	)	
	)	
Abbott Laboratories	)	**NOTICE OF VIOLATION and**
North Chicago, Illinois	)	**FINDING OF VIOLATION**
	)	
	)	**EPA-5-11-IL-03**
Proceedings Pursuant to	)	
the Clean Air Act	)	
42 U.S.C.§§ 7401 et seq.	)	

NOTICE AND FINDING OF VIOLATION

Abbott Laboratories (you or Abbott) owns and operates a pharmaceutical manufacturing plant located at 1401 Sheridan Road in North Chicago, Illinois (facility). The facility manufactures bulk pharmaceutical active ingredients.

The U.S. Environmental Protection Agency (EPA) is sending this Notice of Violation and Finding of Violation (NOV/FOV) to notify you that we have found the facility to be noncompliant with its: 1) startup, shutdown and malfunction plan (SSM Plan); 2) adsorption cycle time and regeneration frequency provisions; 3) 98 percent hazardous air pollutant (HAP) emissions reduction limit; and 4) HAP mass emission limits. These are violations of Subpart A – General Provisions of Part 63 – National Emission Standards for Hazardous Air Pollutants (NESHAP) for Source Categories (Subpart A); Subpart GGG – NESHAP for Pharmaceuticals Production (Subpart GGG); and the Illinois State Implementation Plan (SIP), as incorporated into Abbott's Title V operating permit. These exceedances constitute violations of the Clean Air Act (the Act or CAA).

Section 113 of the Act provides you with the opportunity to request a conference with us to discuss the violations alleged in the NOV/FOV. This conference will provide you a chance to present information on the identified violations, any efforts you have taken to comply and the steps you will take to prevent future violations. Please plan for the facility's technical and management personnel to take part in these discussions. You may have an attorney represent and accompany you at this conference.

Explanation of Violations

The following statutory and regulatory background, factual background and violations are relevant to this NOV/FOV:

Statutory and Regulatory Background

1. The permit and permit conditions relevant to this NOV/FOV are as follows:

   a. The Illinois Environmental Protection Agency (IEPA) issued Title V Permit, Application No.: 96010011 (Title V permit), to the facility on June 27, 2000.

   b. The following emission units are among those permitted to operate at the Abbott facility:

Emission Unit	Description	Date Constructed	Emission Control Equipment
CAPD R-5 & R-6 Fermentation Operations Manufacturing Buildings R-5 and R-6			
Q1789	Methylene Chloride Receiver (Tank 13R, PC-636, Building R-6)	1966	S-32 Carbon Bed
Q2546	Methylene Chloride Wash Tank (Tank 42, PC-632, Building R-6)	1980	S-32 Carbon Bed
Fermentation Operations Manufacturing Area S-32 Tanks			
Q-1798	15,000 Gallon Methylene Chloride Storage Tank (Tank 30, PC-636, Building S-32)	1996	S-32 Carbon Bed Adsorption System
Q-1799	10,000 Gallon Methylene Chloride Storage Tank (Tank 29, PC-636, Building S-32)	1996	S-32 Carbon Bed Adsorption System
Q-1800	5,000 Gallon Methylene Chloride Storage Tank (Tank 31, PC-636, Building S-32)	1996	S-32 Carbon Bed Adsorption System
Q-1801	5,000 Gallon Methylene Chloride Storage Tank (Tank 32, PC-636, Building S-32)	1996	S-32 Carbon Bed Adsorption System
Q-2696	5,000 Gallon Methylene Chloride Storage Tank (Tank 33, PC-636, Building S-32)	1996	S-32 Carbon Bed Adsorption System
T-1925	2,500 Gallon Methylene Chloride Storage Tank (Tank 35, PC-636, Building S-32)	1996	S-32 Carbon Bed Adsorption System

Emission Unit	Description	Date Constructed	Emission Control Equipment
T-1926	2,500 Gallon Storage Methylene Chloride Tank (Tank 34, PC-636, Building S-32)	1996	S-32 Carbon Bed Adsorption System
CAPD S-32AS Fermentation Operations Manufacturing Area S-32 Air Stripper			
LC903705	Methylene Chloride Air Stripper (PC-636, Building S-32)	1996	S-32 Carbon Bed Adsorption System
S-30.2 Fermentation Support Area No. S-30 Methylene Chloride Tanks			
TA-9603	10,000 Gallon Methylene Chloride (Fresh) Storage Tank (Tank TA-9603, Area S-30)	October, 1995	S-32 Carbon Bed Adsorption

Title V

c. Abbott is subject to the following conditions in its Title V permit:

i. 5.2.6 states: "This stationary source, as defined in 40 CFR § 63.1250, is subject to 40 CFR Part 63, Subpart GGG, National Emission Standards for Pharmaceuticals Production. The owner or operator shall certify compliance with the requirements of 40 CFR Part 63, Subpart GGG, as part of the annual compliance certification as required by 40 CFR Part 70 or 71.";

ii. 5.6.2(a)(iii)(C) states: "For each startup, shutdown, or malfunction, the owner or operator shall record all information necessary to demonstrate that the procedures specified in the affected source's startup, shutdown, and malfunction plan were followed, as specified in 40 CFR § 63.6 (e)(3)(iii)...";

iii. 5.4.1 states: "...Compliance with the emission limits may be demonstrated initially through the provisions of 40 CFR § 63.1257 (Test methods and compliance procedures) and continuously through the provisions of 40 CFR § 63.1258 (Monitoring requirements).";

iv. 7.1.1 states: "The exhaust [of the broth aeration from fermentation operations that is vented through the cyclone] is treated with ozone to control odors generated by the fermentation process.";

v. 7.4.3(c), addressing Units CAPD R-5 & R-6, states: "The affected fermentation manufacturing units are subject to the NESHAP for Pharmaceuticals Production, 40 CFR 63 Subparts A and GGG,

specifically 40 CFR § 63.1254(a) for Process Vents at Existing Sources..."; and

vi. 7.6.3(b), addressing Units CAPD S-32AS, states: "The affected air stripper is subject to the NESHAP for Pharmaceuticals Production, 40 CFR 63 Subparts A and GGG, specifically 40 CFR § 63.1254(a) for Process Vents at Existing Sources..."

NESHAP

d. This stationary source, as defined in 40 CFR § 63.1250, is subject to Subpart GGG.

e. Abbott is subject to the following in Subpart GGG:

i. 40 CFR § 63.1259(a)(3)(iii) states: "For each startup, shutdown, or malfunction, the owner or operator shall record all information necessary to demonstrate that the procedures specified in the affected source's startup, shutdown, and malfunction plan were followed, as specified in § 63.6(e)(3)(iii)...";

ii. 40 CFR § 63.1252 states: "...Initial compliance with the emission limits is demonstrated in accordance with the provisions of § 63.1257, and continuous compliance is demonstrated in accordance with the provisions of § 63.1258.";

iii. 40 CFR § 63.1254 states: "...Initial compliance with the required emission limits or reductions in paragraphs (a)(1) through (3) of this section is demonstrated in accordance with the initial compliance procedures described in § 63.1257(d), and continuous compliance is demonstrated in accordance with the monitoring requirements described in § 63.1258.";

iv. 40 CFR § 63.1257(a)(1)(iv) states: "For a carbon adsorption system that regenerates the carbon bed directly onsite in the control device such as a fixed-bed adsorber, the design evaluation shall consider the vent stream flow rate, relative humidity, and temperature and shall establish the design exhaust vent stream organic compound concentration level, adsorption cycle time, number and capacity of carbon beds, type and working capacity of activated carbon used for carbon beds, design total regeneration stream mass or volumetric flow over the period of each complete carbon bed regeneration cycle, design carbon bed temperature after regeneration, design carbon bed regeneration time, and design service life of carbon...";

v. 40 CFR § 63.1258(b)(1)(iv)(A)(1) states that for each regenerative carbon adsorber, the owner or operator shall establish regeneration cycle

characteristics, including minimum regeneration frequency (i.e., operating time since last regeneration);

vi. 40 CFR § 63.1258(b)(1)(iv)(B)(1) states that for each regenerative carbon adsorber, the owner or operator shall monitor and record the regeneration cycle characteristics, including the regeneration frequency (operating time since end of last regeneration);

vii. 40 CFR § 63.1254(a)(3)(i) states that for existing sources, "...uncontrolled HAP emissions from a process vent must be reduced by 98 percent..."; and

viii. 40 CFR § 63.1254(a)(2)(i) states: "Actual HAP emissions from the sum of all process vents within a process must not exceed 900 kilograms (kg) in any 365-day period."

f. 40 CFR § 63.1250(c) states that Table 1 of Subpart GGG specifies and clarifies the provisions of Subpart A that apply to an owner or operator of an affected source subject to Subpart GGG. The provisions of Subpart A specified in Table 1 are the only provisions of Subpart A that apply to an affected source subject to this subpart.

g. Abbott is subject to the following in Subpart A:

i. 40 CFR § 63.6(e)(3)(iii) states: "Furthermore, the owner or operator shall confirm that actions taken during the relevant reporting period during periods of startup, shutdown and malfunction were consistent with the affected source's startup, shutdown and malfunction plan in the semiannual (or more frequent) startup, shutdown, and malfunction report..."

Illinois SIP

h. EPA approved Title 35 of the Illinois Administrative Code (35 IAC) 218.301, governing use of organic material, as part of the Illinois SIP on October 11, 1994. 59 Fed. Reg. 46562.

i. 35 IAC 218.301 provides that: "No person shall cause or allow the discharge of more than 3.6 kg/hr (8 lbs/hr) of organic material into the atmosphere from any emission unit, except as provided in Sections 218.302, 218.303, 218.304 of this Part and the following exception: If no odor nuisance exists the limitation of this Subpart shall apply only to photochemically reactive material."

i. 35 IAC 218.302 stipulates that: "Emissions of organic material in excess of those permitted by Section 218.301 of this Part are allowable if such emissions are controlled by one of the following methods:

a) Flame, thermal or catalytic incineration so as either to reduce such emissions to 10 ppm equivalent methane (molecular weight 16) or less, or to convert 85 percent of the hydrocarbons to carbon dioxide and water; or,

b) A vapor recovery system which adsorbs and/or condenses at least 85 percent of the total uncontrolled organic material that would otherwise be emitted to the atmosphere; or,

c) Any other air pollution control equipment approved by the Agency and approved by the USEPA as a SIP revision capable of reducing by 85 percent or more the uncontrolled organic material that would be otherwise emitted to the atmosphere."

ii. 35 IAC 218.303 stipulates that: "The provisions of Sections 218.301 and 218.302 of this Part shall not apply to fuel combustion emission units."

iii. 35 IAC 218.304 stipulates that: "The provisions of Sections 218.301 and 218.302 of this Part shall not apply to any owner, operator, user or manufacturer of paint, varnish, lacquer, coatings or printing ink whose compliance program and project completion schedule, as required by 35 Ill. Adm. Code 201, provided for the reduction of organic material used in such process to 20 percent or less of total volume by May 30, 1977."

Factual Background

2. Abbott owns and operates a pharmaceutical manufacturing plant located at 1401 Sheridan Road in North Chicago, Illinois.

3. The facility manufactures bulk pharmaceutical active ingredients by fermentation and chemical synthesis; liquid products and ointments; and large and small volume intravenous solutions.

4. Abbott operates emission units that are controlled by a carbon bed adsorption system. It is a three-bed system that typically operates with one bed in adsorption mode, a second bed in regeneration/cool-down mode and the third bed in standby mode.

5. The carbon bed adsorption system controls methylene chloride (also known as dichloromethane) emissions.

6. Compliant operation of the carbon bed adsorption system is based on four parameters: 1) maximum adsorption time during adsorption, 2) minimum quantity of steam during regeneration, 3) minimum bed temperature during steaming and 4) maximum bed temperature after cooling.

7. On February 1, 2010, Abbott submitted a malfunction letter to EPA, Region 5 and IEPA in accordance with 40 CFR § 63.1260(i)(2) and 40 CFR § 63.10(d)(5)(ii).

8. On February 3, 2010, EPA, Region 5 received the malfunction letter from Abbott regarding its facility, which indentified violations that resulted from a malfunction that occurred at the regeneration steaming temperature continuous monitor, along with subsequent malfunctions of the adsorption timer and alarm system. This took place on January 23 and 24, 2010.

9. As a result, on January 23 and 24, 2010, Abbott released 3,000 pounds (1,331 kg) of methylene chloride as excess emissions in a 16.8-hour period. Methylene chloride was released at a rate of approximately 179 pounds/ hour.

Alleged Violations

10. Based on events reported in Abbott's February 1, 2010 letter, EPA finds that Abbott failed to comply with the following:

    a. the procedures specified in the facility's SSM Plan on January 23 and 24, 2010. Abbott is required to manually shut down the process and carbon bed(s) when a malfunction occurs at the automatic control system for carbon bed operation, which was not done in a reasonable period of time;

    b. emission limits demonstrated, in part, by complying with adsorption cycle time and regeneration frequency provisions. Abbott deviated from its allowable maximum adsorption time of 51 minutes and did not meet minimum regeneration frequency requirements on January 23 and 24, 2010;

    c. the facility's HAP reduction limit of 98 percent. Abbott failed to reduce methylene chloride emissions by 98 percent on January 23 and 24, 2010; and

    d. the facility's HAP mass emission limits. Abbott did not comply with methylene chloride mass emission limits on January 23 and 24, 2010. Specifically, Abbott emitted 3,000 pounds (1,331 kg) of methylene chloride as excess emissions over a 16.8-hour period, in violation of its 900 kg in any 365-day period limit and its 3.6 kg/hour (8 pounds/hour) emission rate limit.

11. Abbott's failure to comply with its SSM Plan on January 23 and 24, 2010 is a violation of Subparts A and GGG of the NESHAP, as incorporated into Abbott's Title V operating permit.

12. Abbott's noncompliance with its allowable maximum adsorption time on January 23 and 24, 2010 is a violation of Subpart GGG of the NESHAP, as incorporated into Abbott's Title V operating permit.

13. Abbott's noncompliance with the facility's HAP reduction limit of 98 percent on January 23 and 24, 2010 is a violation of Subpart GGG of the NESHAP, as incorporated into Abbott's Title V operating permit.

14. Abbott's noncompliance with the facility's HAP mass emission limits on January 23 and 24, 2010 is a violation of Subpart GGG of the NESHAP and the Illinois SIP, as incorporated into Abbott's Title V operating permit.

Environmental Impact of Violations

15. These violations have caused excess emissions of HAPs. Violation of the above NESHAP standards resulted in excess HAP emissions that may cause serious health effects, such as birth defects and cancer, and harmful environmental and ecological effects.

1/24/11
Date

Cheryl L. Newton
Director
Air and Radiation Division

CERTIFICATE OF MAILING

I, Betty Williams, certify that I sent a Notice and Finding of Violation, No. EPA-5-11-IL-03, by Certified Mail, Return Receipt Requested, to:

Robert D. Morrison
Divisional Vice President, Environmental, Health, Safety and Energy
Abbott Laboratories
1401 Sheridan Road
North Chicago, Illinois 60048-4000

I also certify that I sent copies of the Notice of Violation and Finding of Violation by first-class mail to:

Ray Pilapil, Manager
Bureau of Air
Compliance and Enforcement Section
Illinois Environmental Protection Agency
1021 North Grand Avenue East
Springfield, Illinois 62702

on the 25th day of January 2011.

Betty Williams
Administrative Program Assistant
Planning and Administration Section

CERTIFIED MAIL RECEIPT NUMBER: 7009 1680 0000 7666 6497